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10/014,750	10/25/2001	Jenny Louie-Helm	3100-0003	1055

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,750	JENNY LOUIE-HELM	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37,39,40 and 45-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37,39,40 and 45-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/03/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of amendment, remarks and IDS filed 1/3/06. Claims 1-37, 39, 40 and 45-56 are pending.

Claim Objections

1. The objection of claim 55 under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or cannot depend from any other multiple dependent claim is withdrawn in view of the amendment to the claim.

Claim Rejections - 35 USC § 102

2. Claims 1-9, 12-16, 18-23, 26-34, 36-40 and 45-55 remain rejected under 35 U.S.C. 102(b) as being anticipated by Shell et al. (US 5,972,389), this Shell referred to as Shell 1

Applicants state that Shell 1 no longer anticipates the claims because the amended claim 1 now recites that "the dosage form exceeds about 1 cm in diameter in a swollen state, and the dosage form swells sufficiently fast to allow retention of the dosage form in the stomach before significant erosion of the dosage form occurs" and further that, Shell 1 does not disclose a dosage form having a diameter exceeding 1 cm after swelling and a dosage form that swells sufficiently fast to allow retention of the dosage form in the stomach before significant erosion.

3. Applicants' arguments filed 1/3/06 have been fully considered but they are not persuasive.

The recitation of "the dosage form exceeds about 1 cm in diameter in a swollen state, and the dosage form swells sufficiently fast to allow retention of the dosage form in the stomach before significant erosion of the dosage form occurs" is a property of the specific dosage form claimed. Shell 1 discloses the dosage form and the swelling ability of the dosage form is the property/characteristic of the dosage form. The dosage form of Shell 1 would undergo the swelling just as the claimed dosage form. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The rejection follows below.

Shell discloses a controlled release oral dosage form that comprises drug particles dispersed in swellable/erodible polymer where the erodible polymer is polyethylene oxide; the dosage form is formulated as tablet or capsule and liposomes or nanoparticles or enteric-coated drug particles are examples of drug containing vesicles that can deliver drugs to the site of interest (abstract, column 1, line 48 to column 2 line 36, column 3, lines 26-44, column 4, lines 5-18, column 7, lines 60-62, column 8, lines 4-55). Ciprofloxacin (column 5, line 10), bismuth subsalicylate, bismuth citrate, antibiotics such as amoxicillin, tetracycline, chlarithromycin, thiamphenicol, metronidazole which are Helicobacter pylori eradicating drugs (column 5, lines 46-49 and claims 6-9), gastric lowering agents such as omeprazole, ranitidine, cimetidine,

famotidine (column 5, lines 49-55) are examples of drugs delivered by the dosage form of Shell. Shell also teaches that nifedipine, acyclovir, alprazolam, phenytoin, carbamazepine, clozapine, lovastatin and nitrofurantoin are other drugs that can be delivered by the vesicle (claim 5).

The molecular weight of the polyethylene glycol in Shell ranges from 1 X 10^5 to 7 X 10^6 kD (claims 3 and 4). The weight ratio of drug to polymer is 2:3 to 9:1 (column 8, lines 26-31).

Claims 2-5 are directed to the property of the dosage and since a property of a composition is not separable from the composition, and in this case the dosage form, Shell meets scope of the limitations of the claims. Claim 1 is a dosage form that comprises a pharmacologically active agent and hydrophilic polymer. In claim 9, the presence of a mixture of polyethylene oxide-co-propylene oxide is optional so that Shell meets the limitation of claims 1. Shell teaches a range of drug to polymer and one of the points in the taught range in Shell anticipates a point in the recited range in claims 13-16. The solubility of the active agent at the designated temperature is a property of the active agent and since no specific active agent is recited, Shell meets the limitations of the claims. Also the molecular weight of the active agent is a property of the active agent and because the instant claims have not recited any drugs that would have the molecular weight recited in instant claim 21 and because some of the drugs recited in the claims are the same as those taught by Shell, Shell meets the limitations of claim 21. Therefore, the teachings of Shell meet the limitations of the claims.

4. Claims 1-7, 10, 12, 17-23 and 45-49 remain rejected under 35 U.S.C. 102(b) as being anticipated by Shell (US 5,007,790), this Shell is referred to as Shell 2.

Applicants' argument with respect to Shell 2 is the same as is for Shell 1 in that dosage

Shell 2 does not disclose that the dosage form swells to a diameter exceeding 1 cm in the

swollen state and the swelling is sufficiently fast enough to allow the retention of the dosage form in the stomach before significant erosion occurs. Therefore, applicants state that Shell 2 does not anticipate the claims.

5. Applicants' arguments filed 1/3/06 have been fully considered but they are not persuasive. The response is the same as above that the recitation that "the dosage form exceeds about 1 cm in diameter in a swollen state, and the dosage form swells sufficiently fast to allow retention of the dosage form in the stomach before significant erosion of the dosage form occurs" is a property of the specific dosage form claimed. Shell 2 discloses the dosage form and the swelling ability of the dosage form is the property/characteristic of the dosage form. The dosage form of Shell 2 would undergo the swelling just as the claimed dosage form. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical composition, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The rejection follows below.

Shell discloses a sustained release oral dosage form in tablet or pill and the dosage form comprises drugs and cross-linked hydrophilic and water swellable polymer (abstract, column 2, line 29 to column 3 line 15 and claims 1-9). The drugs included in the dosage form of Shell are calcium carbonate, cimetidine, ranitidine, indomethacin, ibuprofen, naproxen, prednisone, prednisolone, dexamethasone, piroxicam, aspirin, nifedipine and potassium chloride potassium

supplement (column 2, lines 28-35); carboxymethyl cellulose, alginate, polyvinyl alcohol and chitin (column 3, lines 7-16) are examples of cross-linked polymer.

Claims 2-5 are directed to the property of the dosage and since a property of a composition is not separable from the composition, and in this case the dosage form, Shell meets scope of the limitations of the claims. Claim 1 is a dosage form that comprises a pharmacologically active agent and hydrophilic polymer. The solubility of the active agent at the designated temperature is a property of the active agent and since no specific active agent is recited, Shell meets the limitations of the claims. Claims 45-49 recite the properties and how to optimize the composition, which are not accorded patentable weight to the composition. Also the molecular weight of the active agent is a property of the active agent. Shell reads on the scope of the claims.

6. Claims 1-7, 10, 17-22 and 39 remain rejected under 35 U.S.C. 102(b) as being anticipated by Uemura et al. (US 4,695,467).

Applicants argue that Uemura does not disclose a dosage form that swells and where the diameter of the dosage form exceeds 1 cm in the swollen state.

7. Applicants' arguments filed 1/3/06 have been fully considered but they are not persuasive.

Uemura discloses the claimed dosage form and the recitation that "the dosage form exceeds about 1 cm in diameter in a swollen state, and the dosage form swells sufficiently fast to allow retention of the dosage form in the stomach before significant erosion of the dosage form occurs" is a property of the specific dosage form claimed. Uemura discloses the dosage form and the swelling ability of the dosage form is the property/characteristic of the dosage form.

The dosage form of Uemura would undergo the swelling just as the claimed dosage form. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical product, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The rejection follows bellow.

Uemura discloses sustained release tablet; the tablet comprising disintegrable granules that contain a drug, disintegrating agents selected from starch derivatives, gums, cellulose derivatives and ion exchange resins, and water soluble polymer selected from cellulose derivatives, synthetic water soluble polymers and polysaccharide and excipient (abstract, column 3, lines 10-21). The water-soluble cellulose derivatives are hydroxypropylmethylcellulose, methylcellulose, hydroxypropylcellulose and carboxymethylcellulose; synthetic water-soluble polymers are polyvinylpyrrolidone, cross-linked polyvinylpyrrolidone and polyethylene oxide; and pullulan and dextran are examples of polysaccharides (column 3, lines 33-41).

Claims 2-5 are directed to the property of the dosage and since a property of a composition is not separable from the composition, and in this case the dosage form, Shell meets scope of the limitations of the claims. Claim 1 is a dosage form that comprises a pharmacologically active agent and hydrophilic polymer. The solubility of the active agent at the designated temperature is a property of the active agent and since no specific active agent is

recited and the molecular weight of the active agent is a property of the active agent. The teaching of Uemura meets the limitations of the claims.

Claim Rejections - 35 USC § 103

8. Claims 1, 6, 11, 23-25, 34 and 35 remain rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Patel et al. (US 6,248,363).

Applicants argue that Patel does not disclose a dosage form that whose diameter exceeds 1 cm in the swollen state and where the swelling is sufficiently fast to allow retention of the dosage form in the stomach before significant erosion of the dosage form.

9. Applicants' arguments filed 1/3/06 have been fully considered but they are not persuasive.

The Patel dosage form comprises an active agent incorporated in zein or xanthan gum matrix and this dosage form anticipates the claimed dosage form comprising and active agent incorporated in a matrix of at least one biocompatible hydrophilic polymer (see instant claim 1 as amended). Swelling and erosion are the properties/characteristics of the dosage form of claim 1. The dosage form of Patel would undergo the swelling and erosion just as the claimed dosage form. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical product, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The rejection follows bellow.

Patel discloses a tablet formulation (column 36, line 3) comprising zein or xanthan gum (column 40, lines 63 and 64) and active agents such as paclitaxel, topiramate and metformin (column 5, line 59; column 6, lines 3, 43 and 53; column 9, line 3). Patel anticipates the claims. In the alternate, if the listing of the various drugs do not represent specific disclosure of paclitaxel, topiramate and metformin in tablet formation in xanthan gum containing matrix, it would be obvious that a person of ordinary skill in the art would use any of the disclosed drug in tablet formulation having xanthan gum matrix at the time the invention was made, among the list of disclosed drugs are paclitaxel, topiramate and metformin. Xanthan gum is a biocompatible hydrophilic polymer. One having ordinary skill in the art would have been motivated to prepare the dosage form for oral delivery of paclitaxel, topiramate and metformin.

Claim Rejections - 35 USC § 112

NEW MATTER

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-37, 39, 40, 45-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amended claim 1 recites that the diameter of the dosage form in the swollen state exceeds 1 cm. Further, applicants point to Example 2, Table 3 at page 46 of the instant

specification for support. However, the cited passage of the specification does not provide support for a diameter that exceeds or greater that 1 cm in the swollen state for the following reasons:

The Table 3 show that at time T = 0, the diameter of the dosage form is 18.59 mm (~1.86 cm) for GR/1, 18.68 mm (~1.87 cm) for GR/2, 18.59 mm (~1.86 cm) for GR/3, and 18.67 cm (~1.87 cm) for GR/4. Thus at T = 0, the diameter of the tablet is already exceeding/greater than 1 cm but is limited to about 1.86, 1.68, and 1.87 and not to greater that at least 2 cm. The dimension of the tablet were then taken at 1 hour and 2 hour swelling and the diameter ranges from about 2.1 cm to 2.2 cm for GR/1, about 2.1 cm to 2.2 cm for GR/2, about 2.1 cm to 2.2 cm for GR/3, and about 2.1 cm to 2.2 cm for GR/4. The data in the Table does not provide support for greater that 1 cm that is not limited to 2.2 cm. The data also goes to a maximum of 2 hours.

The recitation that the diameter of the dosage form exceeds 1 cm in the swollen state is new matter.

12. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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